

**Notice of Allowability**

Application No.

10/662,820

Applicant(s)

KOIKE ET AL.

Examiner

Art Unit

Raymond J. Henley III

1614

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed February 28, 2006.
2. ☒ The allowed claim(s) is/are 11 and 17-19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

*DRAWINGS FILED JANUARY 12, 2004 ARE ACCEPTABLE.*

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**RAYMOND HENLEY III  
PRIMARY EXAMINER**

*Au 1614*

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicants' amendment filed February 28, 2006 has been received and entered into the application. Accordingly, claims 11 and 17 have been amended and claims 10 and 16 have been canceled. In view of the such amendments, the objection to claims 10 and 11, as set forth in the previous Office action dated September 29, 2006, is withdrawn. Also, for the reasons presented by Applicants at pages 5-10 of the amendment, which the Examiner adopts, the rejections set forth in the previous Office action under 35 U.S.C. §§ 102 and 13 are also withdrawn and all claims, i.e., claims 11 and 17-19, are deemed allowable.

The following is an expansion of Applicants' remarks which are directed to the proposition that the claims are allowable over Wang et al. In particular, in light of the Examiner's finding that Wang et al. teach the *in vitro* treatment of hepatic carcinoma cells, i.e., growth inhibitory effect on Hep 3B cells, Applicants at page 8 of their amendment offer that such a teaching does not render obvious the presently claimed subject matter because "It is almost axiomatic in pharmaceutical research that an agent's *in vitro* properties are often a poor correlate of their properties *in vivo*", (sentence bridging pages 8-9 of the amendment). If supported by evidence, the Examiner would accept such as an indication that a reasonable expectation of success would have been lacking from a reading of Wang et al. Applicants, however, have not offered any factual support for such a contention. Note MPEP § 2145 where it is set forth: "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience

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is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.”). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.”.

To buttress Applicants’ position, the Examiner here relies on newly cited Johnson et al., (British Journal of Cancer (2000) 84(10), 1424-1431; cited by the Examiner), which does provide sufficient evidence that, especially in the cancer art, *in vitro* results are not sufficient to reasonably support a conclusion that such results would occur *in vivo*. In particular, in the abstract at page 1424, Johnson et al. teach:

“An analysis of the activity of compounds tested in pre-clinical *in vivo* and *in vitro* assays by the National Cancer Institute’s Developmental Therapeutics Program was performed. For 39 agents with both xenograft data and Phase II clinical trials results available, *in vivo* activity in a particular histology in a tumour model did not closely correlate with activity in the same human cancer histology, casting doubt on the correspondence of the pre-clinical models to clinical results. However, for compounds with *in vivo* activity in at least one-third of tested xenograft models, there was correlation with ultimate activity in at least some Phase II trials. Thus, an efficient means of predicting activity in *in vivo* models remains desirable for compounds with anti-proliferative activity in *vitro*.”, (emphasis added).

Accordingly, for the above reasons, the Examiner believes there is insufficient evidence to conclude that Applicants’ claimed subject matter would have been obvious, based on the teachings of Wang et al. For the additional reasons provided by Applicants, all claims are deemed allowable.


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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
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May 8, 2006